PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference MM/03154/PCT	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/EP2004/011349	International filing date *(day/month/year)* 06.10.2004	Priority date *(day/month/year)* 10.10.2003
International Patent Classification (IPC) or national classification and IPC B01L3/14		
Applicant AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO et al.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 1 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the opinion
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
03.08.2005	26.01.2006
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Tiede, R Telephone No. +31 70 340-1090

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/EP2004/011349

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

   ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3 and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4)
   - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages

1-10	as originally filed

Claims, Numbers

4-19	as originally filed
1-3	received on 11.08.2005 with letter of 03.08.2005

Drawings, Sheets

1/3-3/3	as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	3,5-8
	No:	Claims	1,2,4,9-19
Inventive step (IS)	Yes:	Claims	3
	No:	Claims	1,2,4-19
Industrial applicability (IA)	Yes:	Claims	1-19
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

1 The following documents are referred to in this communication:
D1 : US 5 663 051 A (VLASSELAER PETER VAN) 2 September 1997 (1997-09-02)
D2 : US 6 197 579 B1 (HASAN SHIRIN W ET AL) 6 March 2001 (2001-03-06)
D3: WO 02/089725 A (NEXELL THERAPEUTICS INC ;JULIAR RENA (US); ETTEFAGH GUITY (US)) 14 November 2002 (2002-11-14)
D4: US 2002/185457 A1 (SMITH EMERY ET AL) 12 December 2002 (2002-12-12)

2 INDEPENDENT CLAIM 1

2.1 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.
Document D2 discloses (the references in parentheses applying to this document): A disposable container for centrifugation comprising a container with a removable lid (figure 1; columns 5 and 6 and fig. 4 and 6a), said lid comprising three opening with canulas entry ports (72, 76, 77) and a removable stopper (col. 6, line 13; col. 9, line 66) for a vent channel suitable to control venting. Furthermore it discloses that said length of one of said canulas can be varied in length (col. 6, line 33) and in particular it has a length equal in height of the container (fig. 6c and col. 10, lines 1-9).

2.2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not inventive in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parentheses applying to this document): A disposable container for centrifugation comprising a container with a lid (figure 6; column 11), said lid comprising three opening with canulas (92, 78, 82, "luer ports") and a removable stopper (86) for a vent channel, said cap is suitable to control the entry and exit of air. Furthermore, one of said canulas has a length at least equal to that of the height of said container. The device is suitable for control of entry and exit of air and the sterile handling of samples without sterile hoods.

2.3 D1 differs from claim 1 in that it does not disclose a removable lid in combination with the embodiment of fig. 6. However, removable lids are a well known and a common

feature of container for centrifugation (see for example in D1 with respect to embodiments relating to fig. 1-5 and 8), in fact it must be regarded as a commonly known design feature/possibility of such containers. Such a feature can only be regarded as inventive, if the removability of said lid presents unexpected effects or properties. However, no such effects or properties are indicated in the application. Hence, no inventive step is present in the subject-matter of claim 1.

3 DEPENDENT CLAIMS 2, 4, 5-19

Dependent claims 2, 4, 5-19 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT), see citations as given in the International Search Report).

4 DEPENDENT CLAIM 3

The combination of the features of dependent claim 3 are neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:
Subject-matter of claim 3 differs from D1 in that a tap is foreseen at the vent port.

Said vent port solves the problem to simplify operation under sterile conditions (page 2).

Although the problem is well known, D1 does not suggest or imply taps at the vent port in order to regulate ventilation of said container.

Subject-matter of claim 3 is therefore new and inventive (Article 33 PCT).

Re Item VIII.

5 Claims 5-7, 9 relate to features of a needle and a syringe to be used with a container of claim 1. However, according to the wording of claim 1 neither said needle nor said syringe are part of the claimed container - the container is simply suitable to be used

with a needle/syringe. This leaves the reader in doubt as to the meaning and scope of claims 5-7 and eventually also claim 1. Claims 1, 5-7 are therefore not clear (Article 6 PCT).

6 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1-D4 is not mentioned in the description, nor are these documents identified therein.

CLAIMS

1. A disposable container (1) for centrifuging and treating a fluid biological material, said container (1) being provided with an open top end and a closed bottom end (16), characterized in that said top end is provided with a lid (2) having:
   a) a first opening (3) passed through by a first cannula (4) which can be connected operationally to the external environment in order to control the entry and exit of air in conjunction with the transfer of a fluid biological material into or from said container;
   b) a second opening (7) passed through by a second cannula (8) which can be accessed by a hollow needle (9) in order to transfer a fluid biological material into or from said container (1) through said hollow needle (9);
   c) a third opening (11) passed through by a third cannula (12) operationally connected to an attachment (22) able to receive and accommodate one end of a syringe (18) in order to transfer a fluid biological material into or from said container (1) through said third cannula (12); and
   d) the top end (5, 24) of said first cannula (4) is provided with a removable stopper (20, 25) for controlling the entry and exit of air in conjunction with the transfer of a fluid biological material into or from said container.
2. A container (1) according to Claim 1, characterized in that said top end (5) of said first cannula (4) is shaped so as to receive and accommodate one end (19) of a syringe (18) or an adaptor (23) fitted onto said end (19) of said syringe (18) in order to transfer a fluid biological material into or from said container (1) through said first cannula (4).
3. A container (1) according to Claim 2, characterized in that a tap (6) is arranged between said top end (5) and said first cannula (4).

↔ removable
«↔» whose length is at least equal to the height of said container (1);